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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,557

10/03/2005

Christos Tsaklakis

MERCK-2723

3824

23599 7590 11/07/2008  
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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

11/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,557	TSAKLAKIDIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SUN JAE Y. LOEWE	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,23,26,29-33 and 40-60 is/are pending in the application.
- 4a) Of the above claim(s) 26,31,33,40-42,47-55,58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,23,29,30,32,43-46,56,57 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-28-2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1626

**DETAILED ACTION**

1. Claims 1, 23, 26, 29-33 and 40-60 are pending in the instant application.

***Election/Restriction***

2. For the reasons provided below, prosecution is still limited to the elected species. Newly added claims 47-55, 58 and 59 which do not read on the elected species are withdrawn.

***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on August 28, 2008 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS was considered. A signed copy of form 1449 is enclosed herewith.

***Response to Amendment***

4. The amendments to the claims filed on August 28, 2008 have been fully considered. The 35 USC 102 rejection has been obviated and is thus hereby withdrawn.

5. The claim amendments and remarks do not overcome the following grounds of rejection which are maintained and made FINAL: a) 35 USC 112 1<sup>st</sup> paragraph (Section 8); b) 35 USC 112 2<sup>nd</sup> paragraph (Section 9); c) Double Patenting (Section 11).

Note: Section numbers refer to those from the office action dated May 28, 2008.

***Claim Objections***

6. Claims 1, 23, 29, 30, 32, 43-46, 56, 57 and 60 remain objected to for containing non-elected subject matter. Applicant will be entitled to rejoinder and consideration of non-elected species upon allowability of the generic claims.

***Claim Rejections - 35 USC § 112***

7. Below are responses to Applicant's remarks:

- a) "It is noted that the claims refer to solvates, not polymorphs. Thus, arguments regarding polymorphs are not relevant to the present issue. "  
Applicant's arguments are noted. However, absent a specific definition in the disclosure for solvate, the art recognized definition applies to the interpretation of this term. It is recognized in the art that "solvate" refers to polymorphs. Therefore, Applicant's claim to solvates necessarily includes polymorphs of the claimed compounds.
- b) "The formation of solvates is well known within the art. Combining a solvent with a compound to produce of a solvate requires no more than routine experimentation.  
.....

Art Unit: 1626

considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction the experimentation should proceed. ”

Applicant's arguments are noted. However, it is maintained that the formation of polymorphs is not routine experimentation. For the reasons provided in the previous office action (dated May 28, 2008), one of ordinary skill is not able to predict whether solid forms exist for a chemical compound; additionally, one of ordinary skill is not able to predict how to make a particular solid form.

The 35 USC 112 1<sup>st</sup> paragraph rejection is maintained and hereby made FINAL. Claims 1, 23, 29, 30, 32, 43-46, 56, 57 and 60 are rejected.

8. Below is a response to Applicant's remark:

“ As acknowledged in the rejection, the term “derivative” has an art recognized definition. Since the term is well known in the art, one of ordinary skill in the art would find the term to be definite. ”

Applicant's remarks have been considered, however, they are not persuasive in overcoming the rejection for the reasons provided in the previous office action – specifically, the art recognized definition of “derivative” renders the claims indefinite. The 35 USC 112 2<sup>nd</sup> paragraph rejection is maintained and hereby made FINAL. Claims 1, 23, 29, 30, 32, 43-46, 56, 57 and 60 are rejected.

### ***Double Patenting***

9. Applicant's remarks have been considered, however, they are not found to be persuasive.

Applicant is respectfully referred to MPEP 804.I.B.1, excerpts below:

If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer.

Art Unit: 1626

This ground of rejection is maintained as there are other outstanding grounds of rejection remaining.

***Conclusion***

**10. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/

11-5-2008

/Kamal A Saeed, ./

Primary Examiner, Art Unit 1626